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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/009,473 | 11/08/2001 | Michael Hagen | 33,482-00 | 3152 |
| 25291 | 7590 | 05/19/2004 | EXAMINER | |
| WYETH PATENT LAW GROUP FIVE GIRALDA FARMS MADISON, NJ 07940 | | | LE, EMILY M | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1648 | |

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/009,473 | HAGEN, MICHAEL | |
| | Examiner | Art Unit | |
| | Emily Le | 1648 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-87 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-87 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-14, 18-28, 62-64 and 66-68, drawn to a composition and a method of use for the composition, wherein the composition is an antigenic composition comprising an antigen selected from an HIV virus, wherein the peptide of the virus is SEQ ID NO: 1.

Group II, claim(s) 1-14, 18-28, 62-63, 65-67 and 69, drawn to a composition and a method of use for the composition, wherein the composition is an antigenic composition comprising an antigen selected from an HIV virus, wherein the peptide of the virus is SEQ ID NO: 2.

Group III, claim(s) 1-14, 29-31, 32-39, and 70-75, drawn to a composition and a method of use for the composition, wherein the composition is an antigenic composition comprising an antigen selected from an SIV virus, wherein the peptide of the virus is SEQ ID NO: SEQ ID NO: 3.

Group IV, claim(s) 1-14, 29-31, 32-39, and 70-75, drawn to a composition and a method of use for the composition, wherein the composition is an antigenic composition comprising an antigen selected from an SIV virus, wherein the peptide of the virus is SEQ ID NO: SEQ ID NO: 4.

Group V, claim(s) 1-14, 29-31, 32-39, and 70-75, drawn to a composition and a method of use for the composition, wherein the composition is an antigenic composition comprising an antigen selected from an SIV virus, wherein the peptide of the virus is SEQ ID NO: SEQ ID NO: 5.

Group VI, claim(s) 1-14, 29-31, 32-39, and 70-75, drawn to a composition and a method of use for the composition, wherein the composition is an antigenic

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composition comprising an antigen selected from an SIV virus, wherein the peptide of the virus is SEQ ID NO: SEQ ID NO: 7.

Group VII, claim(s) 1-14, 29-31, 32-39, and 70-75, drawn to a composition and a method of use for the composition, wherein the composition is an antigenic composition comprising an antigen selected from an SIV virus, wherein the peptide of the virus is SEQ ID NO: SEQ ID NO: 8.

Group VIII, claim(s) 1-14, 29-31, 32-39, and 70-75, drawn to a composition and a method of use for the composition, wherein the composition is an antigenic composition comprising an antigen selected from an SIV virus, wherein the peptide of the virus is SEQ ID NO: SEQ ID NO: 9.

Group IX, claim(s) 1-14, 51-61 and 82-87, drawn to a composition and a method of use for the composition, wherein the composition is an antigenic composition comprising an antigen selected from an RSV virus.

Group X, claim(s) 1-14, 40-50 and 76-81, drawn to a composition and a method of use for the composition, wherein the composition is an antigenic composition comprising an antigen selected from a bacterium.

Group XI, claim(s) 1-10 and 15, drawn to a composition and a method of use for the composition, wherein the composition is an antigenic composition comprising an antigen selected from a cancer antigen.

Group XII, claim(s) 1-10 and 16, drawn to a composition and a method of use for the composition, wherein the composition is an antigenic composition comprising an antigen selected from an allergen.

Group XIII, claim(s) 1-10 and 17, drawn to a composition and a method of use for the composition, wherein the composition is an antigenic composition comprising an antigen selected from an amyloid peptide protein.

Group XIV, claim(s) 15, drawn to a composition and a method of use for the composition, wherein the composition is an antigenic composition comprising an antigen selected from an antibody to an amyloid peptide protein.

Group XV, claim(s) 1-14, drawn to a composition and a method of use for the composition, wherein the composition is an antigenic composition comprising an antigen selected from a fungi.

Group XVI, claim(s) 1-14, drawn to a composition and a method of use for the composition, wherein the composition is an antigenic composition comprising an antigen selected from a parasite.

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2. In addition to the above listed groups, Applicant must further elect a cytokine, lymphokine, agonist to cytokine, agonist to lymphokine, antagonist to cytokine, or antagonist to lymphokine.

A cytokine is any of numerous hormonelike, low-molecular-weight proteins, secreted by various cell types, that regulate the intensity and duration of immune response and mediate cell-cell communication.

A lymphokine is a cytokine obtained from lymphocytes.

An agonist is a drug capable of combining with receptors to initiate drug actions; it possesses affinity and intrinsic activity.

An antagonist is something opposing or resisting the action of another; certain structures, agents, diseases, or physiologic processes that tend to neutralize or impede the action or effect of others.

Therefore, in view of the definitions provided above, extracted from **Stedman's Medical Dictionary 27th Edition**, the listed molecules lack unity with one another because they do not share a common activity nor do they have a common chemical structure.

3. The inventions listed as Groups I-XVI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The inventions of each listed groups lack unity with one another. The special technical feature of each group is the selected antigen. Each of the selected antigens differs from one another. A viral antigen (Group I-IX) does not have the same chemical

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and biological activities as those of bacterium (Group X), fungi (Group XV), parasite (Group XVI), cancer cell (Group XI), allergen (Group XII), or amyloid peptide (Group XIII-XIV); and vice versa. Therefore, the groups lack unity with one another.

The inventions of Groups I-II lack unity with one another because no significant structural similarity can be readily ascertain from the disclosure of the sequences, thus the individual sequences lacks unity with one another.

The inventions of Groups III-VIII lack unity with one another because no significant structural similarity can be readily ascertain from the disclosure of the sequences, thus the individual sequences lacks unity with one another.

The inventions of Groups XIII-XIV lack unity with one another because the peptides and proteins of Group XIII are structurally different from antibodies of Group XIV.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

E.Le
Emily Le

Shanon Foley
Shanon Foley
Patent Examiner, AU 1648